

REMARKS/ARGUMENTS

The Office Action mailed October 21, 2003, has been received and reviewed. Claims 1, 3 through 11, 13 through 44, 46, 48 through 64, 66 through 74, and 105 through 107 are currently pending in the application. Claims 1, 3 through 11, 13 through 32, 34 through 44, 46, 48 through 62, and 66 through 73 stand rejected. Claims 33, 63, 74, and 105 through 107 have been indicated to contain allowable subject matter. Applicant has amended claims 64 and 69, and respectfully requests reconsideration of the application as amended herein.

In the specification, paragraph spanning pages 18 and 19 has been amended to correct a minor typographical problem. In addition, formal drawings are herewith submitted to replace the informal drawings. No new matter has been added.

35 U.S.C. § 102(e) Anticipation Rejections

Anticipation Rejection Based on U.S. Patent No. 5,882,496 to Northrup et al.

Claims 51, 64, 66, and 73 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Northrup et al. (U.S. Patent No. 5,882,496). Applicant respectfully traverses this rejection, as hereinafter set forth.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Northrup *et al.* does not disclose "a substantially planar substrate" or porous matrices that comprise pores that "communicate with a major surface of said substantially planar substrate," as recited in amended claim 51. Instead, the capillary columns of the apparatus shown in FIG. 8 of Northrup *et al.* are primarily internally confined and completely confined from the major surfaces of the substrate. Since Northrup *et al.* does not disclose each and every element of amended claim 51, the reference does not anticipate amended claim 51. Reconsideration and withdrawal of the rejection is respectfully requested.

Northrup *et al.* does not disclose matrices formed in a substantially planar substrate, said matrices comprising at least two distinct, unconnected porous columns, lengths of said at least two distinct, unconnected porous columns being substantially continuous with a major surface of said substrate, as claimed in amended claim 64. For example, FIG. 8, which is cited by the Office as disclosing distinct, unconnected porous silicon columns or spaced members (page 3 or Paper 29), does not disclose at least two distinct, unconnected porous columns having lengths that are substantially continuous with a major surface of the substrate. Because the reference does not disclose each and every element as set forth in independent claim 64 and dependent claims 66 and 73, the reference does not anticipate the claims.

Reconsideration and withdrawal of the rejection is respectfully requested.

35 U.S.C. § 103(a) Obviousness Rejections

Obviousness Rejection Based on U.S. Patent No. 5,882,496 to Northrup et al. in View of U.S. Patent No. 5,571,410 to Swedberg et al.

Claims 67 and 68 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Northrup et al. (U.S. Patent No. 5,882,496) in view of Swedberg et al. (U.S. Patent No. 5,571,410). Applicant respectfully traverses this rejection, as hereinafter set forth.

M.P.E.P. 706.02(j) sets forth the standard for a Section 103(a) rejection:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, **the prior art reference (or references when combined) must teach or suggest all the claim limitations.** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (Emphasis added).

The 35 U.S.C. § 103(a) obviousness rejections of claims 67 and 68 are improper because Northrup *et al.* does not disclose matrices formed in a "substantially planar substrate," or matrices comprising at least two distinct, unconnected porous columns with lengths that are "substantially continuous with a major surface of said substrate," as claimed in amended

independent claim 64, from which claims 67 and 68 depend. Furthermore, Swedberg *et al.* does not provide the teaching or suggestion absent from Northrup *et al.* Therefore, claims 67 and 68 are not unpatentable over Northrup *et al.* in view of Swedberg *et al.*, because the references, either alone or in combination, do not teach or suggest all of the claim elements.

Moreover, Swedberg *et al.* teaches away from the use of silicon or silicon dioxide based devices. For example, an object of the Swedberg *et al.* invention is to "avoid the inherent chemical activity and pH instability encountered with silicon and prior silicon dioxide-based device substances" (Swedberg *et al.* at col. 4, lines 52-59; *see also*, col. 7, lines 53-56, describing the "substrate" as "**not** silicon or silicon dioxide material such as quartz, fused silica or glass" (emphasis added)). Thus, Swedberg *et al.* teaches away from the use of silicon, thereby precluding any motivation to apply the disclosure of Swedberg *et al.* to the present invention.

In addition, the electrophoresis device illustrated by Northrup *et al.* does not result in elution of the sample, as the electrodes are located adjacent to the ends of the column. Thus, the electromotive force starts and ends prior to the ends of the column. As a result, the sample, presuming that it is somehow placed into the column far enough to become subject to the electromotive force, would migrate only so far as the position of the positive electrode. Furthermore, there is no motivation to place a sample into a column by an unknown means so as to allow it to be subject to an electromotive force. Therefore, adding a capture molecule, which serves a "preconcentration function," as described in Swedberg *et al.* (*see*, col. 33, lines 40-42), to the electrophoresis device taught by Northrup *et al.* would not function. Thus, the references do not make the claimed invention obvious.

Obviousness Rejection Based on U.S. Patent No. 5,482,598 to Isaka et al. in View of U.S. Patent No. 5,882,496 to Northrup et al.

Claims 1, 3 through 5, 7, 9 through 11, 13, 16, 18 through 20, 22 through 25, 29 through 32, 34, 38, 39, 42, 43, 46, 48 through 50, 52, 53, 56, and 69 through 71 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Isaka et al. (U.S. Patent No. 5,482,598) in view of Northrup et al. (U.S. Patent No. 5,882,496). Applicant respectfully traverses this rejection, as hereinafter set forth.

Northrup *et al.* does not teach or suggest "a detector fabricated on said substrate" as recited in claims 1, 3 through 5, 7, 9 through 11, 13, 16, 18 through 20, 22 through 25, 29 through 32, 34, 38, 39, 42, 43, 46 and 48 through 50. Furthermore, Isaka *et al.* does not teach or suggest more than a single column or a detector fabricated on the substrate. For example, the absorption detector cited by the Office (page 7 of Paper 29) is not fabricated on the substrate (*see*, col. 3, lines 25-34 and col. 5, lines 17-30), rather, the detector is located downstream of another, separate, conventional capillary column, which is itself downstream of the column formed in the substrate. Because the references, alone or in combination, do not teach or suggest fabrication of a detector on the substrate, the claims are not obvious in light of the references. Since the references do not teach or suggest all of the claim elements, the references do not render claims 30 through 32, 34, 38, 39, 42, 43, 46, 48 through 50, 52, 53 and 56 obvious.

In view of the foregoing, it is apparent that there are several reasons that the asserted combination of teachings from Isaka *et al.* and Northrup *et al.* does not support a *prima facie* case of obviousness under 35 U.S.C. § 103(a) against any of claims 1, 3 through 5, 7, 9 through 11, 13, 16, 18 through 20, 22 through 25 and 29.

Claims 69 and 70 are directed to an analyte detection apparatus comprising at least one detector proximate said capture substrate. As acknowledged by the Office, Northrup *et al.* does not teach an antibody or antigen as a capture substrate. In fact, Northrup *et al.* does not teach or suggest any capture substrate. Furthermore, Isaka *et al.* does not teach or suggest a capture substrate. The immobilized enzyme of Isaka *et al.* is not a capture molecule as defined in the specification. A capture substrate, as that phrase is used in the specification, includes an antibody, an antigen, or any other substrate material which separates a constituent from a sample on the basis of affinity for the constituent (page 15, line 28 to page 16, line 1 of the specification). Enzymatic modification and release of a compound does not satisfy the definition of a capture molecule, particularly, in view of the enzyme being immobilized throughout the column. Because neither of the references, either alone or in combination, teaches or suggests all of the claim elements, the references do not render claims 69 and 70 obvious.

Claim 71 is directed to an analyte detection apparatus comprising a reaction region along the length of at least one of said at least two porous columns. Neither Isaka *et al.* nor Northrup *et*

al. teach or suggest a reaction region along the length of a porous column. Specifically, the immobilized enzymes of Isaka *et al.*, which are immobilized in an undisclosed relation to the column (presumably, the intent was immobilization along the entire length, thereby making the entire column a reaction region), does not constitute a teaching or suggestion of a reaction region along the length of the column. Therefore, the references, either alone or in combination, fail to teach or suggest all of the claim elements. Thus, the references do not render claim 71 obvious.

Reconsideration and withdrawal of the rejections is respectfully requested.

Obviousness Rejection Based on U.S. Patent No. 5,482,598 to Isaka *et al.* in View of U.S. Patent No. 5,882,496 to Northrup *et al.* and Further in View of U.S. Patent No. 5,571,410 to Swedberg *et al.*

Claims 8, 26 through 28, and 35 through 37 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Isaka *et al.* (U.S. Patent No. 5,482,598) in view of Northrup *et al.* (U.S. Patent No. 5,882,496), as applied to claims 1, 3 through 5, 7, 9 through 11, 13, 16, 18 through 20, 22 through 25, 29 through 32, 34, 38, 39, 42, 43, 46, 48 through 50, 52, 53, 56, and 69 through 71 above, and further in view of Swedberg *et al.* (U.S. Patent No. 5,571,410). Applicant respectfully traverses this rejection, as hereinafter set forth.

As described herein, Swedberg *et al.* teaches away from the use of silicon or silicon dioxide based devices. Moreover, Swedberg *et al.* does not teach or suggest "a detector fabricated on said substrate" or the "porous matrices formed in said substrate and comprising at least two distinct, unconnected capillary columns." As described herein, neither Isaka *et al.* nor Northrup *et al.* teach or suggest all of these claim elements. Because the references, either alone or in combination, do not teach or suggest all of the claim elements, the references do not render claims 8, 26 through 28, and 35 through 37 obvious.

Reconsideration and withdrawal of the rejections is respectfully requested.

Obviousness Rejection Based on U.S. Patent No. 5,482,598 to Isaka *et al.* in View of U.S. Patent No. 5,882,496 to Northrup *et al.* and Further in View of U.S. Patent No. 5,132,012 to Miura *et al.*

Claims 14, 15, 17, 21, 40, 41, 44, 54, and 55 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Isaka et al. (U.S. Patent No. 5,482,598) in view of Northrup et al. (U.S. Patent No. 5,882,496), as applied to claims 1, 3 through 5, 7, 9 through 11, 13, 16, 18 through 20, 22 through 25, 29 through 32, 34, 38, 39, 42, 43, 46, 48 through 50, 52, 53, 56, and 69 through 71 above, and further in view of Miura et al. (U.S. Patent No. 5,132,012). Applicant respectfully traverses this rejection, as hereinafter set forth.

Claims 21 and 41 are generally directed to a sample separation apparatus, having a vacuum source operatively in communication with a column. Specifically, claim 21 recites "a vacuum source operatively in communication with a second end of said at least one porous region" and claim 41 recites "a vacuum source in communication with at least one of said at least two capillary columns." Neither Isaka *et al.* nor Northrup *et al.* nor Mirua *et al.* disclose a vacuum source operatively in communication with a column. Thus, the references do not disclose all of the claim elements and do not render the claim obvious.

Claims 14, 15 and 17, which depend from claim 1, claims 40, 44, which depend from claim 30, and claims 54 and 55, which depend from claim 51, are further allowable, among other reasons, for depending from allowable claims.

Therefore, Isaka *et al.* in view of Northrup *et al.* and further in view of Miura *et al.* does not render claims 14, 15, 17, 40, 44, 54 and 55 obvious.

Obviousness Rejection Based on U.S. Patent No. 5,482,598 to Isaka et al. in View of U.S. Patent No. 5,882,496 to Northrup et al. and Further in View of U.S. Patent No. 5,536,382 to Sunzeri

Claims 6, 57 through 62, and 72 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Isaka et al. (U.S. Patent No. 5,482,598) in view of Northrup et al. (U.S. Patent No. 5,882,496), as applied to claims 1, 3 through 5, 7, 9 through 11, 13, 16, 18 through 20, 22 through 25, 29 through 32, 34, 38, 39, 42, 43, 46, 48 through 50, 52, 53, 56, and 69 through 71 above, and further in view of Sunzeri (U.S. Patent No. 5,536,382). Applicant respectfully traverses this rejection, as hereinafter set forth.

The Applicant notes that the internal standards of Sunzeri cited by the Office (page 13 of Paper 29), which are included within a sample (col. 9, lines 40-42 of Sunzeri), are inapplicable to

the claimed control column, which is external to an analyzed sample and, thus, an "external standard." Because of the inapplicability of "internal standards," Applicant presumes that the Office intended to cite the phrase "external standards" found at col. 9, lines 29-30 of Sunzeri.

The fact that reference teachings *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916, F.2d 680 (Fed. Cir. 1990). What is lacking in the Office's obviousness analysis is a *reason* why one of ordinary skill would be motivated to select the single phrase, "external standards," from Sunzeri, which discloses conventional capillary electrophoresis and combine that single phrase with Isaka *et al.*'s disclosure of a single column and further combine multiple columns having no output of Northrup *et al.* to arrive at the claimed at least two miniature columns where one column is a parallel control column. Applicant respectfully submits that the only source of motivation to make all of the necessary logical leaps is found in the applicant's specification.

Specifically, Northrup *et al.* and Isaka *et al.* are silent with regard to a control column. Therefore, these references provide no motivation to combine the "external standard" of Sunzeri (col. 9, lines 29-30 of Sunzeri), with a column of Isaka *et al.* and/or Northrup *et al.* Likewise, Sunzeri is silent with regard to miniaturized chromatographic columns. Thus, Sunzeri does not provide motivation to produce a parallel miniature chromatographic column. The only motivation to combine the references appears to the Applicant to be supplied by the person of ordinary skill in the art (page 13 of Paper 29) using impermissible hindsight gained from the Applicant's specification.

Furthermore, Sunzeri's general statement of an "external standard" does not teach or suggest a parallel column, as claimed. Rather, as described in Sunzeri (col. 1, lines 36-48), capillary electrophoresis is conducted along gels that are contained within capillary tubes. Thus, when an "external standard" is used, the "external standard" is run along a separate column from that along which a sample is run. In any event, Sunzeri does not provide one of ordinary skill in the art with any motivation to provide a porous control column as part of a separation apparatus formed in a substrate. Thus, Sunzeri does not motivate a person of ordinary skill in the art to produce an apparatus, as claimed, with a parallel control column.

In addition, conventional chromatography and extremely small, or “micro,” separation apparatus that are *formed in* silicon or other *semiconductor substrates* pertain to somewhat diverse fields of art. Therefore, Applicant submits that Sunzeri is non-analogous art, which may not be properly combined with Isaka *et al.* and Northrup *et al.* to produce a proper § 103(a) rejection.

Reconsideration and withdrawal of the rejection is respectfully requested.

Objections to Claims 33, 63, 74, and 105 through 107/Allowable Subject Matter

The Office Action states that Claims 33, 63, 74, and 105 through 107 “would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, second paragraph, set forth in this Office action” However, there are no rejections under 35 U.S.C. 112 set forth in the Office Action. The applicant presumes that the § 112 rejection would be based on depending from a non-allowed claim. However, claim 105 is an independent claim and claims 106 and 107 depend from independent claim 105. Therefore, claims 105 to 107 should be allowable as written.

With regard to claims 33, 63 and 74, the applicant submits that these claims are allowable, as the independent claims 30, 57 and 64, from which they depend, respectively, are allowable.

CONCLUSION

Claims 1, 3-11, 13-44, 46, 48-64, 66-74 and 105-107 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, she is respectfully invited to contact Applicant’s undersigned attorney.

Serial No. 09/177,814

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Brick G. Power". The signature is fluid and cursive, with a long horizontal stroke at the end.

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Attachments: Replacement Sheet(s) (drawings)

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**APPENDIX A
(Replacement Sheets)**